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STEVEN F. WEINSTOCK  
ABBOTT LABORATORIES  
100 ABBOTT PARK ROAD  
DEPT. 377/AP6A  
ABBOTT PARK, IL 60064-6008

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/30/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/833,914

Applicant(s)

SCHRIMPF et al.

Examiner

Brenda Coleman

Art Unit

1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 18, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 27-40, 71-73, and 76-81 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 80 and 81 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 27, 28, 31, 34, 37, 40, 71-73, and 76-79 is/are rejected.
- 7) ☒ Claim(s) 29, 30, 32, 33, 35, 36, 38, and 39 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

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### DETAILED ACTION

Claims 1, 2, 27-40, 71-73 and 76-81 are pending in the application.

This action is in response to applicants' amendment filed April 18, 2003. Claims 1-31 have been canceled and claims 32-54 are newly added.

#### *Response to Amendment*

Applicants' arguments filed April 18, 2003 have been fully considered with the following effect:

1. With regards to the rejection as being drawn to an improper Markush group, the applicant's failed to comment on the rejection which was made in the last office action.

Claims 1, 2, 71-73 and 76-79 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction requirement. The Markush group represented by the terms A and B have variably different definitions, rendering the claims clearly improper.

2. The applicant's amendments are sufficient to overcome the 35 USC § 112 first paragraph rejection of claims 1, 2, 27-40 and 71-79 of the last office action which is hereby **withdrawn**.

3. With regards to the 35 USC § 112 first paragraph rejection of claims 76-79 of the last office action, the applicants remarks concerning the additional active ingredients of claims 76-79 are acknowledged but not found persuasive. The applicants stated that "the specification details

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characteristics of classes of suitable compounds, e.g. non-steroid anti-inflammatory agents, opioids, tricyclic antidepressants and anticonvulsants, as well as providing specific, individual examples of suitable additional active ingredients". However, page 5, line 9 through page 6, line 13 only specifically describes a few agents, i.e. morphine, aspirin, gabapentin or pregabalin. Classes of compounds such as non-steroid anti-inflammatory agents, opioids, tricyclic antidepressants and anticonvulsants is not sufficient to provide an enabling disclosure for the complex compositions claimed herein. The magnitude of these classes are very large. Furthermore, a composition containing an additional active ingredient may be classified based on the additional active ingredient and not the compounds of formula IV. For example morphine would control the classification of any composition containing a compound of formula IV.

Claims 76-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no definition in the specification for the possible additional active ingredients in claims 76-79, i.e. non-steroid anti-inflammatory agent, an opioid, a tricyclic antidepressant or an anticonvulsant.

In view of the amendment dated April 18, 2003, the following new grounds of rejection apply:.

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***Claim Rejections - 35 USC § 112***

The following is as a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain as a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 27, 28, 31, 34, 37, 40, 71-73 and 76-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the definition of R<sub>1</sub> where the moieties are unsaturated phthalazine (first moiety in line 1 on page 5) and thien-2-ylpyridyl (second moiety in line 2, page 5), furan-2-ylpyridyl (third moiety in line 2, page 5), thien-3-ylpyridyl (fourth moiety in line 2, page 5), furan-3-ylpyridyl (first moiety in line 3, page 5) where the bicyclic rings are substituted in the 5-position by R<sub>5</sub> and in the 6-position by R<sub>4</sub> are not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

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- a) Claim 71 is vague and indefinite in that it is not known what is meant by a composition comprising a compound of Claim 1.

***Claim Objections***

6. Claims 29, 30, 32, 33, 35, 36, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Allowable Subject Matter***

7. Claims 80 and 81 are allowed. None of the prior art of record nor a search in the pertinent art area teaches the compositions and method of use of (cis)-3-(5,6-dichloro-3-pyridinyl)-3,6-diazabicyclo[3.2.0]heptane as claimed herein.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman  
Primary Examiner AU 1624  
June 27, 2003